

**Supplemental
Notice of Allowability**

Application No.

09/936,205

Examiner

HOPE A. ROBINSON

Applicant(s)

SMITH ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/29/10.
2. ☒ The allowed claim(s) is/are 9 and 19-21.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>9/17/10</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/25/02</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Hope A. Robinson/
Primary Examiner, Art Unit 1652

SUPPLEMENTAL EXAMINER'S AMENDMENT

1. This is a Supplemental Notice of Allowability to correct a typographical error in the previous Notice mailed on September 27, 2010.
2. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
3. Authorization of this Examiner's amendment was given in a telephone interview with Mr. John Isacson on September 17, 2010.
4. The Claims have been amended as follows:

9. (Currently Amended) A method for preparing an organ by perfusion prior to transplantation or storage of the organ comprising:

[[(I)]] providing a [[n]] preparation to ameliorate ischemic reperfusion injury;
[[prevention preparation for]] and

[[perfusion of]] perfusing an organ prior to transplantation or storage of the organ,
wherein the [[ischemic reperfusion injury prevention]] preparation comprises:

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[[A]] i) a soluble polypeptide [[,]] that has the amino acid sequence of SEQ ID NO:1 or

ii) a soluble polypeptide consisting of the amino acid sequence of amino acids 2-197 and 199-215 of SEQ ID NO:1, wherein the soluble polypeptide is conjugated to myristoyl; and wherein perfusion comprises a non-reducing flush storage solution, wherein the flush storage solution is a perfusion solution; that comprises potassium citrate, sodium citrate, mannitol, and magnesium sulphate; and wherein the preparation maintains the complement inhibitor activity of the soluble polypeptide.

[[consists of: a fragment of complement receptor 1 (CR1) conjugated to myristoyl and a basic amino acid sequence, wherein said fragment has complement inhibitory activity, wherein the soluble polypeptide is SEQ ID NO:1, and wherein the CR1 fragment is amino acid residues 2-197 of SEQ ID NO:1 and the basic amino acid sequence is amino acid residues 199-215 of SEQ ID NO:1; and

(B) a physiologically acceptable and non-reducing flush storage

solution, wherein the flush storage solution is a kidney perfusion solution, that comprises potassium citrate, sodium citrate, mannitol, and magnesium sulphate; and

(11) perfusing the organ with the ischemic reperfusion injury prevention preparation, wherein the organ contains the ischemic reperfusion injury prevention preparation while isolated and prior to implantation, and the ischemic reperfusion injury prevention preparation retains the complement inhibitory activity of the soluble polypeptide.]]

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

6. Claims 9 and 19-21 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652